d) Remarks

Summary of the Office Action

Claims 1-28 are pending in this application.

Claims 9-12, 14 and 17 have been withdrawn as directed to a non-elected species.

Claims 1-3 and 18 have been rejected as anticipated by Calabria U.S. Patent 5,284,473 ("Calabria").

Claims 1-8, 13, 15, 16 and 18-28 have been rejected as obvious over Bagaoisan et al. U.S. Patent No. 6,398,773 ("Bagaosian") in view of Muni et al. U.S. Patent No. 6,454,741 ("Muni").

Applicant's Response

Applicant has amended claims 1 and 18 to clarify the structure of the claimed invention and further distinguish it from that of Calabria, Bagaosian and and Muni.

Specifically, applicant has amended claim 1 to recite that the "***catheter [has] having proximal a end, ... a blood outlet port at the proximal end, [and] ... an occlusive member affixed to the distal end of the catheter at a location proximal of the distal inlet port ...***" and that "***the blood intake port [is] configured to induce venturi-assisted retrograde flow in a treatment vessel so that blood entering the lumen flows from the distal inlet port to the blood outlet port.***" Support for these recitations is provided in the specification, e.g., at page 7, lines 19-24, page 8, line 22 to page 9, line 10 and FIGS. 1-3. Advantageously, as described in the specification at page 9, lines 11-20, this configuration provides emboli removal from a treatment vessel at a physiologically mediated flow rate, and ***without*** the application of suction at the proximal end of the patent (compare to Bagaosian at col. 9, lines 5-9).

By contrast, the device in the Calabria patent is directed to providing perfusion during angioplasty. Specifically, the devices in the Calabria patent are directed to ways of causing blood entering the holes in the lateral surface of the catheter (proximal to the balloon) to exit the distal end of the catheter at higher rates. Accordingly, the Calabria device includes "perfusion assist tube 20" through which blood or saline is injected under pressure to entrain blood entering lumen 3 to exit the catheter through outlet orifice 5 (See FIGS. 1 and 2). The venturi restriction 70 in the embodiment of FIG. 3, and Coanda profiles used in the embodiments of FIGS. 4 and 5 all are directed to causing blood to flow from lateral inlet ports 12 ***towards outlet orifice 5 at the distal end***.

The Calabria device does not anticipate amended claim 1, because catheter is configured to cause blood to flow in the ***wrong direction*** within the catheter relative to applicant's invention. Specifically, blood flow in the Calabria device is from the proximal lateral holes to the distal outlet orifice, whereas in applicant's invention flow is through the distal inlet port and lateral holes towards the ***proximal*** end of the catheter. This difference is reflected in the structure of the two catheters - Calabria has no proximal blood outlet port, and indeed the perfusion assist tube 20, venturi 70 and Coanda profile structures described in the reference urge blood in a ***proximal to distal*** direction.

In order to use the Calabria device in the manner contemplated by the methods of the present invention, one would have to ***discard*** the specific structures ***added*** in that patent to enhance flow. There is no suggestion in the prior art, absent hindsight gleaned from the present application, to undertake such a modification. Indeed, it is established precedent that it cannot be obvious to modify the prior art in a manner that

renders that art useless for its intended purpose. Just such a modification of the Calabria device would be required to arrive at applicant's invention. Moreover, the Calabria devices do not anticipate applicant's claimed method as recited in claim 18, and indeed could not even be used in the claimed method without substantial modification as described above.

Bagaosian, alone or in combination with Muni, also does not render obvious applicant's invention as recited in amended claims 1 and 18. Those amended claims recite that the occlusive member is affixed to the distal end of the catheter ***at a location proximal of the distal inlet port***. By contrast, the balloon in Bagaosian and Muni is disposed on a separate balloon catheter inserted through a guide catheter or aspiration catheter. The occlusive element is ***not*** affixed to a catheter with the holes in the lateral surface and a distal inlet. In fact, if the balloon in the Bagaosian and Muni devices were affixed to the aspiration catheter rather than a separate balloon catheter, the balloon could not then prevent upstream migration of the emboli to be retrieved. See Bagaosian, e.g., at col. 3, lines 28-53.

In view of the foregoing amendment to claims 1 and 18, it becomes plain that neither reference includes lateral intake holes located proximal of a balloon, which is itself proximal of a distal inlet. The side holes depicted in FIGS. 2 and 8C of Bagaosian are stated to be in the ***aspiration catheter***, not the balloon catheter. Alternatively, if interpreted as in the Office action, then the devices of Bagaosian and Muni lack a distal inlet port located distal of the occlusive member, as required by the amended claims.

For the foregoing reasons, applicant's invention is not obvious from Bagaosian or Muni, separately or in combination. There is no suggestion in the prior art to modify

the devices described in those references in a way that renders those devices unfit for their intended purposes. In fact, established precedent dictates that such modifications would not support a conclusion of obviousness.

The reason why the references cannot be combined to arrive at applicant's invention is even more clear when the objectives of the prior art devices are compared to applicant's invention. Bagaosian and Muni are directed to using balloon catheters to segregate a portion of a vessel so that debris generated during use of a therapy catheter ***proximal to the balloon*** is not carried upstream. A separate aspiration catheter is then inserted along the balloon catheter and negative suction is used to aspirate the blood and debris captured behind the balloon.

Applicant's device, on the other hand, is designed so that the balloon, which is affixed to the catheter shaft, may be disposed in an ostium of a vessel to segregate a treatment vessel from a host vessel. Therapeutic instruments may then be disposed through a lumen of the catheter to perform actions that generate debris ***distal to the balloon***. Once the therapeutic instrument(s) are withdrawn, blood enters the catheter from the host vessel and flows towards the proximal end of the catheter. This blood flow in turn induces suction at the distal inlet port that draws debris and emboli, ***located distal to the balloon***, into the inlet port, and establishes retrograde flow in the treatment vessel. This method, as recited in claim 18, is in no way suggested by the Bagaosian or Muni devices, singly or in combination.

Applicants respectfully submit that amended claims 1 and 18 patentably distinguish over the prior art, and thus dependent claims 2-8, 13, 15, 16 and 19-28 also patentably distinguish over the prior art for at least the same reasons.

Applicants submit that claim 1 is generic to the embodiments claimed in withdrawn claims 9-12, 14 and 17, and respectfully requests that those dependent claims be rejoined in this application.

CONCLUSION

In view of the foregoing, applicants respectfully submit that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,

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